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UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE: INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

Civil Action No.: 14-cv-00360-AJB-MDD

Danitta Rinder, Individually and as Special Administrator for the Estate of Gregg Rinder v. Merck Sharp & Dohme Corp.; H.D. Smith Wholesale Drug Co.; Smith Medical LLC; Wolters Kluwer Health, Inc., and Wolters Kluwer United States Inc.

MDL NO. 2452

Case No. 13-MD-2452

DEFENDANT WOLTERS KLUWER HEALTH, INC.'S MEMORANDUM IN SUPPORT OF ITS MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT

Hon. Anthony J. Battaglia

Date: May 22, 2014

Time: 2:00 p.m.

Courtroom: 3B

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTRODUCTION

Defendant Wolters Kluwer Health, Inc. ("WKH") respectfully requests that the Court dismiss with prejudice Danitta Rinder's claims against it pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, both because: (1) Rinder fails to allege facts sufficient to state a claim, and (2) the claim that Rinder attempts to assert against WKH is not viable as a matter of law. In addition and independently, WKH requests that the Court dismiss with prejudice Rinder's claims because they are barred by the applicable statute of limitations.

BACKGROUND

Plaintiff Danitta Rinder alleges that her deceased spouse, Gregg Rinder (the "Decedent") suffered pancreatic cancer as a result of an adverse reaction to the prescription drug Januvia, which is generically known as dipeptidyl peptidase-4 (DPP-IV) ("Januvia"). (First Am. Compl., attached hereto as **Exhibit A**, ¶¶ 1, 5, 6.)[1] Plaintiff alleges that if the Decedent had been "adequately" warned of the

[1] On November 27, 2013, WKUS and WKH filed in the Circuit Court of Cook County, Illinois motions to dismiss the First Amended Complaint. Briefing on those motions was stayed pending the court's decision on a motion to sever and a motion to dismiss based on forum non conveniens filed by Merck, Sharp & Dohme Corp. On January 30, 2014, the Circuit Court of Cook County, Illinois issued an order severing the claims of Plaintiff Diane M. Celeste, individually and as special administrator for the estate of Frederick Celeste and Plaintiff Adelma Holzbaur from Rinder's claims, and dismissed Celeste's and Holzbaur's claims on the basis of forum *non conveniens.* On January 31, 2014, Merck removed this action to the United States District Court for the Northern District of Illinois. On February 13, 2014, this action was conditionally transferred to this Court as a tag-along action.

alleged risk of pancreatic cancer associated with Januvia, he would not have taken the medication. (*Id.* at ¶ 59.)

The First Amended Complaint ("FAC") suggests that three groups of defendants are responsible for Plaintiff's injuries – Merck Sharp & Dohme Corporation ("Merck"), the manufacturer of Januvia; H.D. Smith Wholesale Drug Company and Smith Medical Partners (together "H.D. Smith"), distributors of prescription drugs; and WKH, a publisher of drug information databases, including the patient education monograph ("PEM") information allegedly provided to Mr. Rinder by his pharmacy. Plaintiff also purports to bring claims against Wolters Kluwer United States Inc. ("WKUS"), a separate entity from WKH that is not owned by or the owner of WKH and not involved in publishing drug information, let alone PEM information.[2]

To be clear, Rinder does not specifically allege that WKH was involved in the process of developing, testing, manufacturing, or marketing Januvia.[3] (*See id.* at ¶¶ 23-33; 215-260.) Instead, she alleges that WKH is a publisher of drug

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[2] WKUS's unique arguments in support of its Motion to Dismiss are made in its separate contemporaneously filed Memorandum. WKUS also joins in each of WKH's arguments set forth herein in further support of its motion to dismiss.

[3] Rinder's undifferentiated allegations that "all" Defendants: (a) were aware, before Januvia was approved by the FDA, that the drug increases the risk of pancreatic cancer in diabetic patients; (b) promoted Januvia as a safe and effective treatment for diabetic patients; (c) withheld risk information from the FDA in order to avoid delaying approval of Januvia; and (d) failed to perform adequate safety testing on Januvia, are plainly frivolous as to the non-manufacturer defendants, including WKH and WKUS and should be disregarded. (*Id.* at ¶¶ 48, 50-51, 55.)

information, which, along with alleged publications by other defendants, Rinder vaguely describe as "labels, patient education monographs ("PEM"), patient inserts, warnings, and literature."[4] (*Id.* at ¶ 23.) Although Rinder also suggests that WKH's drug information was generally used by the "medical community," "medical professionals," and the Decedent's "prescribing physicians," the only specific allegations regarding distribution of WKH's drug information to the Decedent relate to its use by the Decedent's pharmacies. (Compare *Id.* at ¶¶ 24, 29, 31, 33, with *id.* at ¶¶ 25-26.)

Rinder obliquely alleges that WKH:

> breached its duty of care, by directly or indirectly, negligently and/or defectively, authoring, analyzing, creating, compiling, designing, drafting, disseminating, distributing, editing, evaluating, marketing, modifying, publishing and supplying prescription drug information, labels, patient education monographs, patient inserts, warnings and literature that were unsuitable for their intended purpose of warning consumers about the risks and side effects of Januvia, particularly the risks and side effects relating to pancreatic cancer.

(*Id.* at ¶¶ 28, 220, 244.) The FAC further alleges that WKH knew, through some unidentified means, that "incomplete, inaccurate, and misleading information and warnings [were] disseminated in their drug information, labels, patient education

[4] The FAC does not identify any alleged publications by name or title or explain which publications are attributable to which defendants. To the extent Rinder suggests that WKH had any role in creating and disseminating Januvia's FDA-mandated package insert, which is published by the manufacturer and approved by the FDA, that is plainly incorrect. *See generally* Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321, *et seq.*

monographs, inserts, warnings and literature for Januvia . . . ." (*Id*. at ¶¶ 30, 222, 246.)

WKH allegedly contracted with pharmacies to provide patient education information, including information about Januvia, that pharmacies could provide to consumers when filling prescriptions. (*Id.* at ¶¶ 23, 26.) The pharmacies used by the Decedent, which Rinder does not name as defendants or even identify in the FAC, allegedly provided the Decedent with Januvia informational materials authored by WKH. (*See id*. at ¶¶ 25-26.) It is not clear why Rinder thinks that WKH provided PEM information to any of these pharmacies, and she does not attach any of the Januvia PEMs that would presumably show who did publish that information.[5]

LEGAL STANDARD

To avoid dismissal under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim "has facial plausibility when the plaintiff pleads factual content that allows the Court to draw the reasonable inference" – based on the Court's "judicial experience and common sense" – that "the defendant is liable for the misconduct alleged." *Id*. Legal conclusions are not

[5] Had Plaintiff done ***any*** pre-suit investigation, he would know that Rinder's pharmacy, which has been identified in discovery responses, licensed PEM information from First DataBank, Inc., a competitor of WKH.

entitled to a presumption of truth, and the Court should disregard conclusory allegations or legal characterizations cast in the form of factual allegations. *Id.* "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements do not suffice." *Id.* Thus, a plaintiff must plead facts and may not rely on mere conclusory statements in order to survive a motion to dismiss. *See, e.g.*, *Brooks v. Ross*, 578 F.3d 574, 581-82 (7th Cir. 2009) (rejecting as a conclusory formulaic recitation of cause of action where complaint alleged defendants "knowingly, intentionally and maliciously prosecuted" plaintiff in retaliation for exercising constitutional rights); *McCauley v. City of Chicago*, 671 F.3d 611, 616-17 (7th Cir. 2011) (rejecting conclusory allegations, which "are not entitled to assumptions of truth" pursuant to *Twombly* and *Iqbal*). Instead a court must "draw on its judicial experience and common sense" in making a "context specific" determination as to whether a complaint states a plausible claim for relief. *Iqbal*, at 679. Rule 8(a) of the Federal Rules of Civil Procedure "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." *Id.* at 678-79.

ARGUMENT

I. THE LAW DOES NOT RECOGNIZE PLAINTIFF'S CLAIMS AGAINST WKH AS VALID.

A. Rinder's Negligence Claim (Count 22) Should Be Dismissed Because WKH Owed Rinder No Duty Of Care As A Matter of Law.

The existence of a duty of care is one of the "essential element[s]" of a negligence claim and is a question of law for the Court. *Ballog v. City of Chicago*, 2012 IL App. (1st) 112429 ¶ 19-21 (1st Dist. 2012). If there is no duty to the plaintiff, there can be no claim for negligence. *Id.* at ¶ 21. WKH had no relationship with Rinder or the Decedent and, under settled law, did not owe them any duty of care. Neither did WKH voluntarily assume any obligations to Rinder or the Decedent not otherwise imposed by law. In any event, any negligence claim is foreclosed by the learned intermediary doctrine.

B. There Is No Relationship Between Plaintiff Or The Decedent And WKH That Supports The Existence of A Duty of Care.

The touchstone of the duty analysis is the relationship between the parties – that is, "whether defendant and plaintiffs stood in such a relationship to each other that the law imposed upon defendant an obligation of reasonable conduct for the benefit of plaintiffs." *Happel v. Wal-Mart Stores, Inc.*, 199 Ill.2d 179, 186 (2002). Here, there simply was no relationship between Plaintiff and WKH. Plaintiff does not and cannot allege that the Decedent bought any product from WKH, that the Decedent had any contractual relationship with WKH, or that WKH had any

information about the Decedent. Instead, Plaintiff tries to concoct a legal duty by combining WKH's direct or indirect relationships with a pharmacy and the Decedent's separate relationship with the same pharmacy. These allegations are simply insufficient to give rise to any legal duty between *WKH* and the *Plaintiff*.

Indeed, several courts have already concluded that PEM publishers like WKH do not owe patients a duty of care when they have no direct relationship with those patients. In *Cheatham v. TEVA Pharmaceuticals USA*, another case involving WKH, the court rejected a claim that WKH had a legal duty to disclose possible side effects associated with the prescription drug Tramadol in WKH's Tramadol PEM. 726 F. Supp. 2d 1021 (E.D. Ark., May 20, 2010). The court first noted that WKH's role in the alleged injury was limited:

> WKH had nothing to do with the manufacture, distribution, or testing of Tramadol. WKH publishes drug information in electronic databases, including patient drug education ("PDE") information. . . . WKH provides pharmacies like USA Drug with generalized summary information about prescription drugs for use by pharmacists in their provision of counseling to patients . . . .

Id. at 1022. Furthermore, it was "undisputed that WKH had no direct relationship to [plaintiff] Geri Cheatham . . . [and] made no effort to provide her with a detailed or individualized warning regarding the drug prescribed by her physician and obtained from USA Drug." *Id.* at 1023. These facts – the same facts here – were fatal to the plaintiff's negligence claim.

Likewise, in *Rivera v. First DataBank, Inc.*, the court found that a monograph publisher owes no duty to individual patients. 115 Cal. Rptr. 3d 1 (Cal. Ct. App. 2010). According to the court, a PEM publisher does not have the same duties as a drug manufacturer, who must provide the medical community or the pharmacy that dispenses a drug with warning information required by the FDA. *Id.* at 8. The court further noted that, on its face, the PEM was intended to be limited in scope, as it included an express statement that the PEM was "a summary and does not contain all possible information about this product. For complete information about this product or your specific health needs, ask your health care professional." *Id.*

Similarly, in *Wilkow v. Drug Fair, Inc.*, a court applying New Jersey law found that a PEM publisher owed no duty of care to an individual patient because the Plaintiff had no relationship to the publisher. *Wilkow*, 1999 WL 33645139, Tr. Trans. at 9 (N.J. Super. Ct. Oct. 22, 1999) (attached hereto as **Exhibit B**). The court rejected the plaintiff's contention that PEM information about the drug Dynabac was insufficient because it did not include a particular warning about taking Dynabac on an empty stomach. *Id.* at 4.

These decisions are consistent with case law holding that pharmacies generally do not owe individual patients a duty to identify all of the potential adverse effects associated with a prescription drug. *See, e.g.*, *Happel*, 199 Ill.2d at 189 (2002); *Cottam v. CVS Pharmacy*, 436 Mass. 316, 322-23, 764 N.E.2d 814,

820-21 (Mass. 2002). It cannot be that WKH, which merely licenses generalized, publically available prescription drug information to pharmacies that then provide that information directly to patients, is burdened with a greater duty of care than that imposed on the pharmacy itself.

C. <u>WKH Did Not Voluntarily Assume Any Duty To Plaintiffs</u>.

In order to show a voluntarily assumed duty, a plaintiff must identify a specific undertaking made by a defendant that forms the basis for the plaintiff's negligence claim. *See, e.g., Frye v. Medicare-Glaser Corp.*, 153 Ill. 2d 26, 32 (1992). In the FAC, Plaintiff alleges that WKH voluntarily assumed a duty to warn of all dangers associated with Januvia: (a) by virtue of publishing drug information for a profit; (b) through unidentified provisions in contracts with pharmacies; or (c) through general statements about drug information (not patient education information specifically) on WKH's website. (Ex. A at ¶¶ 24, 26-27, 32.) None of these allegations is sufficient to establish a voluntarily assumed duty that can support Plaintiff's negligence claim.

First, courts have repeatedly rejected efforts to conjure a voluntarily assumed duty to provide *complete* warnings by virtue of an undertaking to provide *some* warning information. For example, the plaintiff in *Cheatham* argued that because WKH provided certain patient education information about Tramadol, WKH also had an obligation to warn against ingesting Tramadol with other prescription drugs. 726 F. Supp. 2d at 1024. The court disagreed. Reasoning that (a) "a disclaimer at

the top of the monograph advised [plaintiff] that it was 'not intended to cover all possible uses, directions, precautions, drug interactions, or adverse effects' or to be used as 'specific medical advice;'"[6] (b) there was "nothing extensive or detailed about the generic drug information provided in the monograph;" and (c) the monograph was "not intended to supplant" warnings from plaintiff's physician or pharmacist, the court concluded that it would not impose on WKH the duty requested by the plaintiff. *Id*. *See also Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981) ("[W]e do not believe that by preparing such brochures and distributing them to physicians [to be provided to patients], a prescription drug manufacturer undertakes to render a voluntary service so as to invoke the 'voluntary duty' rule.").

Similarly, in *Frye*, the Illinois Supreme Court rejected a plaintiff's claim that a pharmacy voluntarily assumed a duty to warn a patient as to all potential risks associated with the drug Fiornal – including the risk of drinking alcohol while taking the drug – by virtue of providing a warning that Fiornal could cause drowsiness. 153 Ill. 2d at 33. The court reasoned that imposing the expansive duty proposed by plaintiff would deter pharmacists from giving any warnings, thus depriving consumers of beneficial information. *Id*. An expansive duty to warn also "would be difficult from a practical standpoint," the court explained, because of the sheer number of potential side effects potentially associated with a prescription

[6] Indeed, such a disclaimer is included in all of WKH's PEM information.

drug. *Id*. at 33, 560-61. Ultimately, the court noted that the warning provided was accurate, and concluded that this satisfied "the extent of [the defendant's] undertaking." *Id*. at 33-35, 561; *see also, Kasin v. Osco Drug, Inc.*, 312 Ill. App. 3d 823, 829 (2d Dist. 2000) (pharmacist providing an information sheet regarding a drug did not voluntarily undertake to warn of all possible side effects of drug); *AB v. Ortho-McNeil-Janssen Pharms.*, No. 649, 2013 Phila. Ct. Com. Pl. LEXIS 84, at *19 (April 5, 2013) (attached as **Exhibit C**) (rejecting plaintiffs' claims pursuant to Section 324A of the Restatement (Second) of Torts that a publisher of medical information voluntarily assumed a manufacturers' duty to warn the medical community about potential side effects of a drug).

The same reasoning applies here. WKH's Januvia PEM information includes the same disclaimer language identified in *Cheatham* that belies any allegation that WKH undertook a broader, voluntarily assumed duty to include all potential side effects in the PEM. As in *Cheatham*, the PEMs are short, supplemental, summary documents that can be printed from WKH's database, and there is nothing to suggest that the Januvia PEMs contain (or undertook to contain) extensive or detailed information about a drug. 726 F. Supp. 2d at 1024. Finally, there are sound practical and public policy reasons for not extending WKH's voluntary provision of warnings regarding some side effects associated with Januvia into a broad duty to provide warnings about all potential side effects.

Second, Plaintiff's allegations about unidentified provisions in WKH's pharmacy contracts do not show any specific undertaking made by WKH to Plaintiff's pharmacy, let alone to the Decedent himself. Similarly, the language Plaintiff cites from WKH's website does not show any specific undertaking to the Decedent himself. (Ex. A at ¶ 32.) The website statements discuss WKH's drug information generally, including "drug product and pricing information" and "clinical decision support databases that identify drug conflicts." (*Id.*) They do not relate solely to the specific information that is the subject of Plaintiff's allegations in the FAC, namely "consumer oriented information written to educate patients about their drug therapy," and they certainly do not suggest that any such "consumer oriented information" is intended as a complete account of all potential side effects of any prescription drugs. (*Id.*)

In any event, generalized marketing materials alone cannot create a legal duty. *New Jersey Carpenters Health Fund v. Philip Morris, Inc.*, 17 F. Supp. 2d 324, 343 (D.N.J. 1998) (noting lack of authority to support claim that a duty could be created by company's general public statements); *Texas v. The American Tobacco Co.*, 14 F. Supp. 2d 956, 973 (E.D. Tex. 1997) ("Although Texas courts have adopted § 323 of the Restatement as a basis of liability, they have not extended it to create a duty based upon corporate statements or advertising."); *Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc.*, 171 F.3d 912, 936 (3rd Cir. 1999); *Gunsalus v. Celotex Corp.*, 674 F. Supp. 1149, 1157 (E.D.

Pa. 1987); *see also, e.g., Wright v. Brooke Group Ltd.*, 652 N.W.2d 159, 177 (Iowa 2002); *Solis v. Lincoln Elec. Co.*, 2006 WL 1305068, at *6 (N.D. Ohio May 10, 2006). And, of course, Plaintiff does not allege that the Decedent ever actually saw or relied upon WKH's website, which is unsurprising, since WKH does not license its PEM information directly to individual patients.

D. The Learned Intermediary Doctrine Bars Plaintiff's Negligence Claim.

Even if Plaintiff could show that WKH owes Plaintiff a duty of care either as a matter of law or by virtue of WKH's voluntary conduct – which she cannot – any negligence claim is barred by the learned intermediary doctrine. Prescribing physicians, who are best positioned to make an informed, individualized medical judgment based on their knowledge of both the patient and the drug, have primary responsibility for providing a patient with medical advice, including advice on the side effects associated with a prescription drug. *Frye*, 153 Ill.2d at 33-35; *Abramowitz v. Cephalon, Inc.*, 2006 WL 560639 (N.J. Super. Ct. Law Div. Mar. 3, 2006). By virtue of this responsibility, other entities in the pharmaceutical industry have limited obligations: Drug manufacturers have a duty to warn the medical profession, but not individual patients, about potential side effects. *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill. 2d 507, 519 (1987). Although pharmacists are required to provide counseling to patients under state pharmacy regulations, they do not owe patients a duty to identify all adverse effects potentially associated with a

particular drug. *See, e.g. Frye*, 153 Ill. 2d at 32-34. *Happel*, 199 Ill.2d at 189, 766 N.E.2d at 1125; *Cottam*, 436 Mass. at 322-23, 764 N.E.2d at 820-21.

Against this backdrop of descending duties, with a primary focus on the prescribing physician, there is no basis for imposing on a publisher of generalized PEM information a broad duty to provide complete side effect information. *See, e.g.*, *Cheatham*, 726 F. Supp. 2d at 1024 ("It would be contrary to existing legal principles to impose upon WKH a duty greater than the pharmacy that filled the prescription and provided the monograph to Geri Cheatham."). That is especially true since a publisher of generalized information, unlike a physician or pharmacist, does not and cannot have any direct knowledge of the often critical, individualized information about any particular patient.

E. The First Amendment Limits Any Duty Imposed On Publishers And Authors.

The absence of any legal duty by a PEM publisher is independently justified by the First Amendment, which generally protects truthful statements made to a general audience. *Rivera*, 187 Cal. App. 4th at 715-17. In *Rivera*, the plaintiff alleged claims for negligence and breach of contract arising out of the content of the defendant's PEM publication on the drug Paxil. *Id*. at 715. The court reasoned that publishing falls within the purview of the First Amendment, and that the contents of the monographs – which related to treatment for depression – concerned a matter of public interest. *Id*. at 716. As the Supreme Court recognized, "speech

on 'matters of public concern' . . . is 'at the heart of the First Amendment's protection.'" *Dun & Bradstreet, Inc. v. Greenmoss Builders, Inc.*, 472 U.S. 749, 758-59 (1985) (footnotes and citations omitted).

Rivera is entirely consistent with other First Amendment precedent. The Supreme Court has ***never*** allowed a claim against a publisher based on truthful speech on a matter of public concern. *See Cox Broad. Corp. v. Cohn*, 420 U.S. 469, 491 (1975); *Okla. Publ'g Co. v. District Court*, 430 U.S. 308, 310 (1975); *Landmark Commc'ns, Inc. v. Virginia*, 435 U.S. 829 (1978); *Smith v. Daily Mail Publ'g Co*., 443 U.S. 97, 102 (1979); *Florida Star v. B.J.F.*, 491 U.S. 524, 541 (1989); *see also Miami Herald Publ'g Co. v. Tornillo*, 418 U.S. 241, 258 (1974) (protecting publishers' editorial judgments) (citation and internal quotation omitted). Instead, the court has cautioned that "state action to punish the publication of truthful information seldom can satisfy constitutional standards." *Bartnicki v. Vopper*, 532 U.S. 514, 527 (2001).[7]

[7] Decisions by federal and state courts are in accord. *See, e.g., Winter v. G.P. Putnam's Sons*, 938 F.2d 1033, 1037 (9th Cir. 1991) ("Were we tempted to create this duty, the gentle tug of the First Amendment and the values embodied therein would remind us of the social costs."); *Rosenberg v. Harwood*, 2011 WL 3153314, at *1 (Utah Dist. Ct. May 27, 2011) (finding Google to be a publisher of Google Maps and noting significant policy considerations against imposing duty on publishers); *Abraham v. Entrepreneur Media, Inc.*, Case No. 09-CV-2096, 2009 WL 4016515, at *1 (E.D.N.Y., Nov. 17, 2009) (noting that New York courts and the courts of numerous other jurisdictions have "uniformly" held that publishers owe no duty to the public); *Brandt v. Weather Channel, Inc.*, 42 F. Supp. 2d 1344, 1346 (S.D. Fla. 1999) (It is "well established [law] that mass media broadcasters and publishers owe no duty to the general public who may view their broadcasts or

Even where publishers have been sued based on allegations that their publications misled readers about medical safety, courts have consistently refused to impose liability, especially where competing scientific theories are at issue. *See, e.g.*, *Smith v. Linn*, 48 Pa. D.&C. 3d 339, 1988 WL 156664 (Pa. Com. Pl. 1988) (holding in negligence case against diet-book publisher accused of publishing dangerous recommendations that no duty consistent with the First Amendment could flow from publisher to general public); *Gorran v. Atkins Nutritionals, Inc.*, 464 F. Supp. 2d 315, 326-27 (S.D.N.Y. 2006) (same); *Roman v. City of New York*, 110 Misc. 2d 799, 802 (N.Y. Sup. 1981) ("One who publishes a text cannot be said to assume liability for all 'misstatements,' said or unsaid, to a potentially unlimited public for a potentially unlimited period."). This protection flows, in part, from courts' rightful concern as to the chilling effects of exposing publishers to civil liability based on allegations similar to those currently at issue. *See Smith*, 48 Pa. D.&C. 3d at 351; *McMillan v. Togus Reg'l Office, Dep't of Veterans Affairs*, 294 F. Supp. 2d 305, 318 (E.D.N.Y. 2003) (emphasizing the "chilling effects of unnecessary litigation" in dismissing, on First Amendment grounds, claims against the National Academy of Sciences that were based on "what plaintiff thinks the Academy failed to include in the Report."), *aff'd*, 120 Fed. Appx. 849 (2d Cir.

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read their publications."); *Yuhas v. Mudge*, 129 N.J. Super. 207, 210 (App. Div. 1974) (publisher owed no duty of care to individual reader because holding otherwise would "have a staggering adverse effect on the commercial world and our economic system").

2005); *Barden v. HarperCollins Publishers, Inc.*, 863 F. Supp. 41, 45 (D. Mass. 1994) (a publisher of medical information is not accountable in tort for the omission of material that Plaintiffs allege it "should have" included for her benefit).

Like the Paxil PEM at issue in *Rivera*, WKH's Januvia PEM information relates to a matter of public concern – treatment of diabetes – and is protected by the First Amendment. Although Plaintiff vaguely alleges that WKH's Januvia PEM information was not "truthful" (*see, e.g.*, Ex. A at ¶ 31), she does not identify a single statement in the PEM that allegedly was false. Instead, reading the allegations as a whole, Plaintiff's claim, at best, is that the PEM omitted specific information about the alleged risk of pancreatic cancer.[8] (*See id.* at ¶¶ 28, 220, 244 ("patient education monographs . . . were unsuitable for their intended purpose of warning consumers about the risks and side effects of Januvia, particularly the risks and side effects relating to pancreatic cancer").) As such, there is no basis for Plaintiff to contend that the Januvia PEM is not entitled to First Amendment protection because it was not truthful.[9] In light of the constitutional protection afforded to WKH's speech, Plaintiff's claims must fail.

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[8] Of course, Plaintiff fails to explain how WKH knew or could have known about risks that Plaintiff also alleges Merck supposedly concealed from the FDA and the medical community. (*Id.* at ¶ 15.)

[9] Plaintiff may argue, to no avail, that WKH's Januvia PEM is entitled to some lesser protection because it is commercial speech. First, it is not commercial speech – that is expression related to the economic interests of the speaker and its audience, usually in the form of a commercial advertisement for the sale of goods and services. *Bolger v. Youngs Drugs Prods. Corp.*, 463 U.S. 60, 66-67 (1983); *Central*

II. PLAINTIFF'S CLAIMS SHOULD ALSO BE DISMISSED BECAUSE SHE FAILS TO ALLEGE FACTS SUFFICIENT TO STATE A CLAIM.

Even assuming Plaintiff theoretically could state a claim against WKH under some set of facts, her claims still fail based on the insufficient and conclusory allegations actually included in the FAC. Reading the allegations most favorably to Plaintiff, she alleges:

- WKH published PEM information regarding Januvia for profit (*Id.* at ¶ 24);
- WKH contracted with Plaintiff's pharmacy to provide it with PEM information (*Id.* at ¶ 26);
- WKH intended that pharmacies could provide that PEM information to their customers to warn them about potential risks and side effects associated with the drug (*Id.* at ¶ 23);
- The PEM information was unsuitable for its intended purpose of warning consumers about the potential risks of pancreatic cancer associated with Januvia (*Id.* at ¶ 28);
- The Decedent received the PEM information from the pharmacy (*Id.* at ¶ 25);
- It was foreseeable that the Decedent would rely on the PEM information and that he might suffer injury if that information was not "complete" (*Id.* at ¶ 31); and
- The Decedent was unaware of the potential risk of pancreatic cancer because it was not adequately disclosed in the PEM information (*Id.* at ¶ 33).

Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557, 561 (1980). WKH's Januvia PEM does not promote Januvia, and is only provided to the patient by the pharmacist after Januvia has been purchased. (*See* Ex. A at ¶ 25). Although PEM data is sold, published information does not become commercial speech simply because it is published for profit. Moreover, as discussed above, even if the PEM information were commercial speech, it is entitled to First Amendment protection because Plaintiff has alleged no facts showing that the information was false, as opposed to allegedly incomplete. *See, e.g.*, *In re R.M.J.*, 455 U.S. 191, 203 (1982); *Bates v. State Bar*, 433 U.S. 350, 383 (1977); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976).

A number of crucial supporting facts, however, are missing from these superficial allegations, including:

- What the PEM actually said;
- That the Decedent actually read the PEM;
- How or why the statements in the PEM were legally deficient;
- How other discussions or additional information about Januvia that the Decedent had with or received from his doctors or pharmacists (parties notably absent from this litigation) affected his decisions;
- What information about Januvia – other than PEM information – was actually published by WKH, and provided to the Decedent's prescribing physicians or the medical community at large (*Id.* at ¶¶ 29, 33.)[10];
- What information about Januvia, including the FDA-mandated insert, was published by entities *other* than WKH and provided to the decedent's prescribing physicians or the medical community at large;
- Any basis for concluding that the Decedent *actually* (as opposed to foreseeably) read or relied upon the PEM; or
- How the Decedent could reasonably rely on the generalized summary information in the PEM as a comprehensive source of information regarding potential side effects associated with Januvia, particularly in light of the fact that the monographs expressly state that they are not comprehensive and that he presumably would have received other earlier, and more comprehensive and particularized information from his physicians.

These are not just details for Plaintiff to figure out in discovery – they are facts are critical to WKH's ability to respond to and defend against Plaintiff's claims. Without more, Plaintiff's complaints are insufficient on their face to satisfy even

[10] Allegations about unidentified information, other than PEM information, that WKH allegedly provided to the Decedent's physicians are impossibly vague and specious on their face. Among other things, Rinder does not identify the title of any such publications, who used them, when they were used, how they were used, or how they effected the total mix of information available to any physician.

the most liberal interpretation of the fact pleading required by Illinois law and the complaint should be dismissed.

III. PLAINTIFF'S CLAIMS SHOULD BE DISMISSED BECAUSE THEY ARE BARRED BY THE STATUTE OF LIMITATIONS.

Plaintiff's claims, both individually and as the representative of her deceased husband Gregg Rinder, should be dismissed because they are barred by the two-year statutes of limitations governing personal injury and product liability claims. *See* 735 ILCS 5/13-202; 735 ILCS 5/13-213(d) (West 2008). A cause of action for personal injuries generally accrues at the time the plaintiff is injured. *Golla v. General Motors Corp.*, 167 Ill. 2d 353, 360 (1995). Under the "discovery rule," commencement of the statute of limitations may be postponed until the injured plaintiff knows or reasonably should know that he has been injured and that his injury was wrongfully caused. *Id.* at 361. However, when it reasonably appears that an injury was wrongfully caused, the plaintiff becomes obligated to inquire further to determine whether an actionable wrong was committed. *Nolan v. Johns-Manville Asbestos*, 85 Ill. 2d 161, 171 (1981). This duty of reasonable inquiry is triggered when information about the effectiveness of a drug is available in the public domain. *Gredell v. Wyeth Labs., Inc.*, 2005 WL 4774219, at *11, 35-37 (Ill. Cir. Ct. Jun. 10, 2005).

Here, Plaintiff alleges that Gregg Rinder was prescribed Januvia on or about May 19, 2008, and continued using the drug through at least January 19, 2010. (Ex.

A at ¶ 5.) She further alleges that Gregg Rinder was diagnosed with pancreatic cancer on or about March 28, 2010 and died on May 21, 2010. (*Id*. at ¶ 6.) Plaintiff commenced this action on March 29, 2013, more than three years after the March 2010 diagnosis.

In an apparent effort to avoid the statute of limitations, Plaintiff includes the unsupported FAC assertion that she was "unaware Januvia caused his pancreatic cancer until within two years of the filing of this complaint and … could not have discovered any defect in Januvia or that Januvia caused his pancreatic cancer sooner through the exercise of reasonable care." (*Id.*) Yet nowhere in the FAC does Plaintiff explain what inquiry she undertook to determine the cause of her husband's alleged injuries, how or when she learned of the alleged causal connection between Januvia and those injuries, or what prevented her from making that connection sooner. Plaintiff's threadbare allegations that the discovery rule applies are insufficient to avoid application of the statute of limitations. *See, e.g.*, *Kartch v. Retirement Bd. of Firemen's Annuity & Benefit Fund of Chicago*, 265 Ill. App. 3d 618, 622 (1st Dist. 1994), (quoting *Pratt v. Sears Roebuck & Co.*, 71 Ill. App. 3d 825, 829 (1st Dist. 1979)) ("A plaintiff requesting the application of the discovery rule must plead facts necessary to explain why the cause of action was not discovered earlier."); *Chicago Park Dist. v. Kenroy, Inc.*, 58 Ill. App. 3d 879, 888 (1st Dist. 1978) ("[T]he City had the burden of alleging that it neither knew nor could have known, of the facts supporting its cause of action until some time after

the basis for the action was completed. Absent such specific pleading, the 'discovery rule' is inapplicable.")[11].

IV. PLAINTIFF'S REMAINING CLAIMS FAIL BECAUSE THEY ARE DERIVATIVE OF THE FLAWED NEGLIGENCE CLAIMS.

Plaintiff also attempts to assert claims for "Wrongful Death – Negligence" and survival. These counts are not independent causes of action but, instead, are derivative of her negligence claim. *See, e.g., Williams v. Manchester*, 228 Ill.2d 404, 420-21 (2008) (recognizing that to maintain wrongful death action, decedent must have been able to bring, at time of death, an action for damages resulting from occurrence, and thus the action is derivative in nature); *Cretton v. Protestant Mem. Med. Ctr., Inc.*, 371 Ill. App. 3d 841, 846 (5th Dist. 2007) (noting that survival action preserves right of action for personal injury that accrued before death); *Janetis v. Christensen*, 200 Ill. App. 3d 581, 585 (1st Dist. 1990) (survival action is a derivative action for decedent's injury). As such, the failure of Plaintiff's negligence claim disposes of her wrongful death and survival claims as well, and those claims should be dismissed.

[11] Plaintiff's survival claim also does not survive the statute of limitations. *See* 735 ILCS 5/13-209(a)(1) (West 2000) (with respect to survival claims, if a person entitled to bring an action dies before statute of limitations expires, representative may commence an action before the expiration of that time or within one year from the decedent's death, whichever is later).

CONCLUSION

For all of the foregoing reasons, Defendant Wolters Kluwer Health, Inc. respectfully requests that this Honorable Court dismiss, with prejudice, the FAC as against Wolters Kluwer Health, Inc.

Dated: March 19, 2014

Neal, Gerber & Eisenberg LLP

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CERTIFICATE OF SERVICE

Karl R. Barnickol, an attorney, hereby certifies that he caused a copy of the foregoing **Defendant Wolters Kluwer Health, Inc.'s Memorandum in Support of its Motion to Dismiss** to be served on:

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via electronic filing using the United States District for the Southern District of California CM/ECF system which sent notification of such filing on the 19th day of March, 2014.

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